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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,416	07/07/2003	David Scott Wishart	080586-1.00US	7969
20350 7590 03/22/2007 TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			EXAMINER WHALEY, PABLO S	
			ART UNIT	PAPER NUMBER
			1631	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/22/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/615,416

Applicant(s)

WISHART ET AL.

Examiner

Pablo Whaley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 51-64 is/are pending in the application.
- 4a) Of the above claim(s) 63 and 64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 51-62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u>                                    | 6) <input type="checkbox"/> Other: _____                          |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :11/02/2005, 07/18/2005, 01/20/2004, 12/24/2003, 08/20/2003, 08/14/2003 .

## DETAILED ACTION

### *APPLICANT'S ELECTION*

Applicants' election of Group I drawn to Claims 51-61 with traverse, filed 12/14/2006, is acknowledged. Applicants' arguments that the method claim should necessarily include a search for the apparatus claim is not persuasive, as the apparatus contains distinct features that are not required by the claimed method as set forth in the previous office action. However, the Examiner has determined that the search for claim 62 is not a search burden. Therefore claim 62 is grouped with claims 51-61 for examination. Claims 63-64 are hereby withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 12/14/2006.

### *CLAIMS UNDER EXAMINATION*

An action on the merits of Claims 51-62 follows.

### *INFORMATION DISCLOSURE STATEMENT*

The information disclosure statements filed 11/02/2005, 07/18/2005, 01/20/2004, 12/24/2003, 08/20/2003, and 08/14/2003 have been considered in full.

### *DRAWINGS*

Drawings filed 7/7/2003 have been accepted.

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*PRIORITY*

Priority to Canadian application 2,331,116, filed 1/15/2001 and Canadian PCT/CA01-01544, filed 11/01/2001, and US application 10/416,988, filed 5/16/2003 has been acknowledged. However, if applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 119, a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

**CLAIM REJECTIONS - 35 USC § 101**

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 51-62 are rejected under 35 U.S.C. 101 because these claims are drawn to non-statutory subject matter. The instant claims are generally directed to a computer implemented process for producing a trace file for use in spectrum analysis. A statutory process must include a step of a physical transformation of matter, or produce a concrete, tangible, and useful result [State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998)], [AT&T Corp. v. Excel Communications Inc. (CAFC 50 USPQ2d 1447 (1999))].

The instant claims comprise steps that clearly do not result in a physical transformation of matter (e.g. Fourier transform, filtering, and phasing of spectral data), and therefore encompass non-physical method steps that may be practiced inside of a computer (i.e. *in-*

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*silico*). Where a claimed method does not result in a physical transformation of matter, it may be statutory where it recites a result that is concrete (i.e. reproducible), tangible (i.e. communicated to a user), and useful result (i.e. a specific and substantial). In the instant case, the claims lack a tangible result as nothing is communicated to a user such that it is useful to one skilled in the art. For these reasons, the instant claims are not statutory.

This rejection could be overcome by amending the claims to recite a computer readable medium comprising a program containing instructions, wherein the program result is "displayed" or "outputted" (e.g. output to a user, a display, a memory, or another computer, etc.), or by amending the claims to include a step of a physical transformation of matter (e.g. assay). For an updated discussion of statutory considerations with regard to non-functional descriptive material and computer-related inventions, see the Guidelines for Patent Eligible Subject Matter in the MPEP 2106, Section IV.

### **CLAIM REJECTIONS - 35 USC § 101**

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

### ***LACK OF UTILITY***

Claims 51-62 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either an asserted utility or a well-established utility.

In the instant case, the claimed invention is not supported by a well-established utility. The instant claims are generally directed to a process for producing a trace file for use in spectrum analysis, with no limitation as to the type spectral analysis. The specification discloses

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several general disciplines where the instant invention may be "useful" [0008] and [0009], such as NMR and the quantification and identification of biological compounds. However, the disclosed utilities are not specific to the instant claims. For these reasons, the claimed subject matter does not have a specific, substantial, and credible utility.

Claims 51-62 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial, and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

#### **CLAIM REJECTIONS - 35 USC § 112, 2<sup>nd</sup> Paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 51-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 51 recites a "process for producing a trace file for use in spectrum analysis" in the preamble. However, claimed method steps confusingly do not results in the production of a trace file. Therefore it is unclear in what way the claimed method steps achieve the purpose of the preamble. Clarification is requested via clearer claim language.

Claims 51 and 62 recite a "trace file." As the specification does not provide a limiting definition for this term, it is unclear as to the metes and bounds of said "trace file." Clarification is requested.

Claim 52 recites "to suppress a peak associated with a contaminant." As the parent claim does not recite any previous step directed to a "contaminant", it is unclear in what way this limitation further limits the claimed method step. Correction is requested.

Claim 52 recites "associated with contaminants in said contaminant region." There is lack of antecedent basis for this limitation. Correction is requested.

Claim 53 recites "wherein applying a notch filter comprises producing an adjusted set of notch filter parameters and applying a notch filter employing said adjusted set of notch filter parameters." Applying a notch filter and producing filter parameters are two distinct method steps. As written, it is unclear in what way this limitation further limits said notch filter. Furthermore, it is unclear in what way said "adjusted set of notch filter parameters" has been produced. Clarification is requested. The Examiner has broadly interpreted this limitation for purposes of applying prior art.

Claim 54 recites "wherein applying a notch filter comprises iteratively adjusting said set of notch filter parameters and applying a notch filter....". Applying a notch filter and iteratively adjusting filter parameters are two distinct method steps, therefore it is unclear in what way this limitation further limits said notch filter. Clarification is requested. The Examiner has broadly interpreted this limitation for purposes of applying prior art.

Claim 54 recites "wherein applying a notch filter comprises iteratively adjusting...and applying said adjusted notch filter parameters to a notch filter and applying said notch filter to a selected region until a sum of the absolute values of areas defined by peaks above and below a baseline of said initial spectrum is minimized." There is lack of antecedent basis for "the absolute values of areas defined by peaks above and below a baseline of said initial spectrum." Correction is requested. Furthermore, as notch filters are well-known for removing specific periodic signals, it is unclear in what way applying a notch filter results in a minimization of said



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initial spectrum. The Examiner has broadly interpreted this limitation for purposes of applying prior art.

Claim 60 recites the term "drift effects." As the specification does not provide a limiting definition for this term, it is unclear as to the metes and bounds of said "drift effects." Clarification is requested. The Examiner has broadly interpreted this limitation for purposes of applying prior art.

Claims 53 and 54 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Claims 53 and 54 recite steps directed to "producing an adjusted set of parameters" and "iteratively adjusting" parameters. The omitted essential steps appear to be "defining" filter parameters, and then a step of "comparing" parameters to a baseline, since the instant claims do not indicate which of the preceding steps would indicate filter parameters, and since no baseline is provided such that parameters can be compared to indicate a change. Clarification is requested. The Examiner has broadly interpreted this limitation for purposes of applying prior art.

### CLAIM REJECTIONS - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 51, 52, and 55-62 are rejected under 35 U.S.C. 102 (b) as being anticipated by CCL.NET (<http://www.ccl.net/cca/software/MS-WIN95-NT/MestRe-C/README.shtml>, Published and last modified on Mar. 15, 1997, p.1-7).

CCL.NET teach a computer-implemented process and code (Mestre-C) for manipulating FID spectral data. More specifically, CCL.NET teach the following aspects of claims 51, 52, and 55-62: performing FT (Fourier Transformation) of FID data [p.5]; a plurality of weighting functions and filtering functions including Hanning and Hamming windows [p.5], which is an implicit teaching for a "notch" filter; options for "drift correction" [p.5]; exponential multiplication functions [p.5], which is an implicit teaching for line broadening functions; automatic phase correction of zero and first order correction angles[p.5], which implicitly includes real and imaginary components; manual or automated baseline correction [p.6]; and integration for measuring and normalization (i.e. scaling) of data to user-defined values for peak suppression [p.6]. Furthermore, CCL.NET provide for interactive apodization of spectral data [p.5], which is an implicit teaching for windowing of spectral data.

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 51-59, and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cameron (Mikrochim. Acta, 1987, Vol. III, p.229-239), in view of Otvos (US 5,343,389; Issued Aug. 30, 1994).

Cameron teaches methods and a computer processing system for advanced processing of spectral data. Specifically, Cameron teaches performing the Fourier transformation to obtain an initial spectrum, methods for filtering (i.e. notch filters) and phase correction [p.230, Table 1 and p.232, ¶ 3], algorithms for measuring of spectral data [p.231, ¶ 4], as in claims 51, 52, 53.

Cameron also teaches the following aspects of the instantly claimed invention:

- Basic parameters associated with spectral data and algorithms [p.231, ¶ 4], as in claims 53 and 54.
- Methods for integration of spectral intensity data [Table 1], and filtering methods for optimizing spectral data that has been windowed [p.232, ¶ 3], which equates to a

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teaching for area calculation and “iteratively adjusting” parameters which is as in claim 54.

- Phase correction of spectral data comprising real and imaginary components [Table 1] and [p.238, ¶ 2], as in claim 55.
- Sinc functions for line broadening, broadening functions for removal of negative peaks [p.230, ¶ 2 and 3], and weighted Fourier Transforms [p.232, ¶ 3 and p.233, ¶ 2], as in claims 56 and 57.
- Taking a “section” the spectrum (i.e. windowing) and weighting it (i.e. scaling) [p.232, ¶ 3], and user interfaces for selecting specific spectral data regions [p.239, ¶ 2], as in claims 58, 59.
- Peakheight computation and baseline subtraction [p.232, ¶ 2], which equate to teachings for baseline “correction”, as in claim 61.

Cameron does not specifically teach performing the FT on FID data, as in claim 51. However, Cameron clearly suggests the use of their advanced processing techniques on NMR data [p.233, ¶ 1], which motivates the application of such techniques to FID data.

Otvos teaches methods for processing reference sample FIDs to give an initial frequency-domain spectra for use in spectral analysis, wherein processing operations comprise Fourier transformation, phasing, and baseline correction which are accomplished using standard commercial DISNMR programs [Col. 9, lines 22-35], as in claim 51. Furthermore, Otvos teaches adjusting coefficients to fit calculated lineshapes of NMR spectral data [Ref. Claim 1] and calculation of weighting coefficients for minimizing spectral data [Col. 6, lines 1-11], which makes obvious the manipulation of parameters to improve spectral data as in claims 53 and 54.

Thus it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the spectral processing techniques of Cameron with the FID data where the motivation would have been to remove noise from spectral data [Cameron, p.232, ¶ 3], resulting in the practice of the instant claimed invention. One of skill in the art would have had a reasonable expectation of successfully combining the data set of Otvos with the processing techniques of Cameron as both teach methods for correction of spectral data.

Claims 51-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dunkel (US 5,572,125; Issued Nov. 5, 1996), in view of Oppenheim et al. (Digital Signal Processing, 1975, Prentice-Hall, p.230, 242, and 255-265).

Dunkel teaches methods for correction and automated analysis of NMR spectral data. More specifically, Dunkel teaches the following aspects of the instant claims:

- Obtaining initial spectrum, filtering spectrum (i.e. via baseline subtraction), applying phase function to spectrum [Fig. 14], applied to FID data [Fig. 17], as in claim 51, wherein frequency data spectrum acquired using the complex FT (Fourier Transformation) inherently consists of real and imaginary parts [Col. 3, lines 5-20], as in claim 55.
- Performing the FT on time-frequency data (i.e. FID) to obtain frequency-domain spectral data and retaining at least a portion of said data; selecting a predetermined mathematical model (i.e. filter) of expected spectral data; estimating pre-selected parameters and adjusting said parameters; determining corrected spectral data by applying adjusted parameters representing a fit of said mathematical model to at least a portion of spectral data [Ref. Claim 10], as in claims 53 and 54.

- FT of FID data calculated and weighted sum of spectral data is used for baseline correction, wherein spectrum consists of positive values [Fig. 15], as in claims 56, 58, 59, and 61.
- Lorentzian line broadening functions [Col. 28, ¶ 3], as in claim 57, and correction for frequency drift (i.e. drift effects) [Col. 2, lines 40-47], as in claim 60.
- Computer modules and software for automated analysis of spectral data [Fig. 26] and [Fig. 8], which is an implicit teaching for computer readable medium and code for implemented the above steps, as in claim 62.

Dunkel does not specifically teach a “notch filter.” However, Dunkel does suggest methods for removing specific spectral components using a variety of mathematical models [Fig. 2, 14, 18], and methods for noise reduction (i.e. filtering) [Col. 2, ¶ 3], which motivates to use of band-pass filters (i.e. notch filters).

Oppenheim et al. teach iterative mathematical procedures for designing FIR filters with the smallest stopband approximation errors [p.255-265]. More specifically, Oppenheim et al. teach methods specific parameters for designing band-pass filters (i.e. notch filters) [p.230, Table 5.1] and [Fig. 5.43, 5.45, and 5.46], as in claims 52, 53, and 54. Oppenheim et al. also teach methods for defining spectral windows [p.242], as in claim 58.

Thus it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the spectral processing techniques Dunkel with the additional band-pass filters (i.e. notch filters) taught by Oppenheim et al., where the motivation would have been to used improved FIR filters for removing noise from spectral data, resulting in the practice of the instant claimed invention. One of skill in the art would have had a reasonable expectation of

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successfully combining the digital filters of Oppenheim et al. with the processing techniques of Cameron as both teach methods for correction of spectral data.

### CONCLUSION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached at 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pablo S. Whaley

Patent Examiner

Art Unit 1631

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*Sei A. Chow*  
*Patent Examiner*  
*3/15/07*